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Integrating Lean Concept and Digitalization Approach: A Framework For Novel Predictive Management Excellence In Pharmaceutical Quality

A Synopsis

Submitted in

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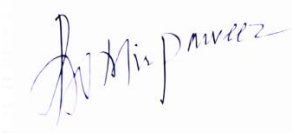
DECLARATION

I. I Mir Parveez Shafi, hereby declare that all the statement made in this application are true, complete and correct to the best of my knowledge and belief and in the event of any information being found false or incorrect or any ineligibility being detected before or after the registration for Ph.D. My candidature is liable to be cancelled and legal action may be initiated against me.

II. I have deposited the required fee, as notified by the University regularly.

III. I have noted that if my application is found incomplete / defective, the same is liable to be rejected summarily and no correspondence will be entertained in this regard.

IV. I have read and agree with the University Revised Ph.D. Ordinance No. 14 and UGC Regulation – 2009, and all the Amened Regulations or newly passed Regulations by the UGC on or before below mentioned date.



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SYNOPSIS

1. Introduction

The pharmaceutical industry is one of the most regulated and quality-sensitive sectors, where ensuring product safety, efficacy, and compliance with international standards is paramount [1]. Quality control and management are very important in the pharmaceutical industry because even small mistakes can have big effects, such as fines from regulators, lost money, and most importantly, health risks for patients. Traditionally, pharmaceutical companies have relied on reactive quality management systems that detect and address defects after they occur[2] . However, with increasing global competition, stringent regulatory requirements, and growing consumer expectations, there is a pressing need to shift towards proactive, data-driven, and predictive quality management frameworks[3].

This research proposes a novel framework that integrates Lean principles with digitalisation approaches to achieve predictive management excellence in the pharmaceutical quality management. Digitalization uses AI, big data analytics, cloud computing, and the Internet of Things to make sure real-time monitoring and predictive decision-making. Lean concepts focus on getting rid of waste, improving workflows, and creating more value[4]. By combining the efficiency-driven philosophy of Lean with the advanced capabilities of digital technologies, this framework aims to revolutionize quality management in the pharmaceutical sector.

The goal is to develop a predictive management system that anticipates quality issues before they occur, ensuring compliance, reducing costs, and improving patient safety.

1.1 Lean Methodology in Pharmaceutical Quality Management

Lean methodology, originally introduced in the manufacturing sector through the Toyota Production System (TPS), aims to streamline processes, eliminate inefficiencies, and create value-driven workflows. Over the years, Lean concepts have been successfully used in many fields, such as healthcare and pharmaceuticals, to boost quality standards and make operations more efficient[5].

1.2 In pharmaceutical manufacturing, Lean concepts play a crucial role in

- **Reducing waste:** Lean identifies and eliminates seven forms of waste, including excess inventory, unnecessary transportation, overproduction, and defects [6].
- **Enhancing workflow efficiency:** By implementing Just-In-Time (JIT) production, pharmaceutical companies can produce drugs more efficiently and reduce lead times[7]**.**
- **Improving product quality:** Lean fosters continuous improvement (Kaizen), ensuring that manufacturing processes are constantly refined to prevent defects[8].
- **Standardizing operations:** The use of standardized work procedures minimizes variability in production, leading to more consistent product quality[9].

While Lean has proven effective in improving operational efficiency, its full potential in pharmaceutical quality management can be realized when combined with digitalization, which enhances visibility, traceability, and predictive capabilities.

1.3 Role of Digitalization in Pharmaceutical Quality Management

The rapid advancement of Industry 4.0 technologies has revolutionized quality management practices across industries, including pharmaceuticals[10]. Digital transformation enables companies to shift from traditional, manual, and paper-based quality management systems to automated, data-driven, and real-time quality monitoring frameworks [11]. Key digital technologies shaping pharmaceutical quality management include:

1. **Artificial Intelligence (AI) & Machine Learning (ML):** AI-driven predictive analytics can identify potential quality deviations before they occur, allowing for proactive interventions rather than reactive problem-solving.
2. **Internet of Things (IoT):** Real-time monitoring of important factors like humidity, temperature, and contamination levels in work environments is made possible by IoT-enabled smart sensors[12].
3. **Cloud-Based Quality Management Systems (QMS):** Digital QMS platforms allow seamless data integration, document management, and compliance tracking across global manufacturing sites[13].
4. **Blockchain for Data Integrity:** Block chain technology ensures secure, tamper-proof records of quality measurement, improving transparency in supply chain management[14].
5. **Automated Compliance & Regulatory Reporting:** Legal requirements like Good Manufacturing Practices (GMP), FDA 21 CFR Part 11, and ISO 9001 are followed by using digital tools that automate compliance paperwork.
6. By integrating these technologies, pharmaceutical manufacturers can enhance process efficiency, reduce human errors, and strengthen regulatory compliance, ultimately leading to improved product quality and patient safety.

1.4 Predictive Management for Quality Enhancement

Traditional quality management in pharmaceuticals is often reactive, meaning that quality defects are addressed only after they have been detected through testing, audits, or customer complaints. This approach, while necessary, is not sufficient in today's fast-paced and highly regulated environment. Predictive management, enabled by Lean and digital technologies, shifts the focus from defect detection to defect prevention, ensuring that potential risks are mitigated before they impact production or compliance [15].

Key Benefits of Predictive Management in Pharmaceutical Quality:

1. **Early Detection of Quality Issues:** AI and machine learning algorithms look at both old and new production data to find trends that could point to problems or defects[16].
2. **Reduced Product Recalls:** By proactively identifying quality risks, predictive management minimizes the likelihood of product recalls, which can be costly and damaging the company reputation[17].
3. **Enhanced Process Efficiency:** Data-driven insights enable companies to optimize workflows, reducing downtime and improving overall equipment effectiveness (OEE).
4. **Better Regulatory Compliance:** Predictive models help pharmaceutical companies stay ahead of evolving regulatory requirements, ensuring continuous compliance with global standards[18].
5. **Cost Reduction:** Preventing quality defects before they occur reduces waste, production rework, and non-compliance penalties, leading to significant cost savings[19].

The implementation of predictive management requires a cultural shift within pharmaceutical organizations, where data-driven decision-making and continuous improvement become central to quality assurance strategies.

1.5 Challenges and Future Prospects

Despite its numerous benefits, the adoption of Lean and digitalization in pharmaceutical quality management faces several challenges:

- **High Initial Investment:** Digital transformation and Lean methods need a lot of money up front to be spent on technology, equipment, and training for the workforce.
- **Integration Complexity:** Pharmaceutical companies often operate across multiple sites with legacy systems that may not be easily integrated with digital tools [20].
- **Regulatory and Compliance Barriers:** Ensuring that digital systems meet stringent regulatory requirements, such as FDA, EMA, and WHO guidelines, can be challenging.
- **Data Security and Privacy Concerns:** As things become more digital, strong cybersecurity steps are needed to keep private pharmaceutical data safe[21].

However, as the industry moves towards Pharmaceutical 4.0, where smart factories and AI-driven quality management become the norm, the integration of Lean and digitalization is expected to become a standard practice. Future advancements in AI, IoT, and blockchain will further enhance predictive management capabilities, making pharmaceutical quality management more efficient, reliable, and proactive.

The integration of Lean principles and digitalization provides a powerful framework for predictive management excellence in pharmaceutical quality[22].

While Lean ensures operational efficiency by eliminating waste and standardizing processes, digitalization enhances visibility, traceability, and data-driven decision-making. Together, they enable pharmaceutical companies to move beyond reactive quality control and adopt a proactive, predictive approach to quality management[23].

As regulatory expectations and market demands continue to evolve, adopting predictive management strategies will be essential for pharmaceutical manufacturers aiming to improve product quality, reduce risks, and enhance overall operational excellence. Companies that embrace this integrated approach will not only achieve superior compliance and efficiency but also gain a competitive advantage in an increasingly complex and globalized pharmaceutical landscape[24].

1.6 Rationale of the Research

The pharmaceutical industry faces growing challenges in maintaining high-quality standards, ensuring regulatory compliance, and minimizing operational inefficiencies. Traditional quality management approaches often rely on reactive measures, leading to costly product recalls, compliance risks, and inefficiencies. The integration of Lean principles and digitalization presents a transformative opportunity to enhance predictive quality management, reducing waste, optimizing workflows, and improving decision-making through automation, real-time monitoring, and advanced analytics[25]. Lean methodology helps eliminate non-value-adding processes, while digital technologies such as Artificial Intelligence, Internet of Things and Big Data Analytics enable predictive insights, proactive risk mitigation, and automated quality control [26]. This research is essential in addressing the industry's transition to Pharma 4.0 and provide roadmap for Pharma 5.0, where interconnected smart systems drive efficiency, sustainability, and regulatory adherence. By integrating Lean-driven continuous improvement with digital advancements, pharmaceutical

companies can significantly enhance operational excellence, minimize compliance risks, and ensure sustainable, cost-effective production [27]. This study contributes to both academic and industry practices by exploring how Lean-digital synergy can establish a predictive, intelligent quality management system, ensuring higher efficiency, better compliance, and superior product quality. This research outlines a roadmap for Pharma 5.0, by establishing a framework for developing key performance indicators, which will guide the integration of advanced digitalization with a human-centric approach, sustainability, and technology-driven decision-making.

1.7 Problem Statement

- ✓ Current challenges in pharmaceutical quality management:
- ✓ Regulatory Compliance and documentation burden.
- ✓ Operational Inefficiencies and waste
- ✓ Data Silos and lack of real-time insights
- ✓ Manual Processes leading to errors and delays
- ✓ Rationalize real-time decision-making

1.8 Justification of the Study

The pharmaceutical industry faces increasing challenges related to quality management, regulatory compliance, operational efficiency, and cost control, necessitating innovative approaches to ensure consistent product excellence. Traditional quality management systems, which are often reactive, result in inefficiencies, compliance risks, and financial losses due to recalls and defects. The integration of Lean methodology and digitalization offers a proactive and predictive quality management approach, enhancing efficiency, reducing waste, and ensuring regulatory compliance through real-time monitoring, AI-driven analytics, and automated quality control processes. This study is justified as it addresses a critical industry need by exploring how Lean principles and digital

transformation can collectively enhance pharmaceutical predictive quality management, and develops & proposes the key performance indicators, which thereby minimizing risks, reducing costs, and improving patient safety. By developing a structured approach that combines these two methodologies, this research provides a novel and scalable solution for pharmaceutical companies striving for sustainable operational excellence and long-term competitive advantage in an increasingly digital and regulated environment.

1.9 Research Objective

- ✓ To evaluate the synergies between Lean principles and digitalisation in pharmaceutical Quality management.
- ✓ Quality Sustainability Planning, Improvement, Control and Monitoring.
- ✓ To design a predictive management framework that integrates Lean and Digitalization for Quality Excellence.
- ✓ To define &propose key performance indicators (KPIs) for Predictive Management.
- ✓ To offer practical guidelines for implementing the framework in real-world scenarios.

1.10 Research Question

1. What is the impact of Lean Principles on pharmaceutical quality sustainability?
2. How can quality sustainability be effectively planned, improved, controlled, and monitored in the pharmaceutical industry?
3. How can an integrated approach combining Lean principles and digitalization enhance quality sustainability and operational excellence?
4. What key performance indicators (KPIs) can be defined and proposed for predictive management in pharmaceutical quality?

2.Review of Literature

2.1Evolution of Lean Principles in Pharmaceutical Quality Management

Januszek et al. (2023) looked into how soft lean practices affect the effects of hard lean practices on performance in the pharmaceutical business.The study looked at 351 pharmaceutical plants and found that management practices like measuring performance, showing results, and giving employees more power weakened the link between strict lean methods and better performance. On the other hand, it was found that putting too much stress on setting goals and standardizing work hurt performance. This research shows how important management styles are for putting lean ideas into practice in pharmacy quality management.

Tetteh-Caesar et al. (2024)did a systematic review of case studies that looked at how Lean 4.0 methods were used in the pharmaceutical business. Their study put together important lessons, benefits, and best practices. It showed that across documented efforts, quality assurance reliability increased by more than 50% and inventory waste decreased by 57%. The study highlighted challenges such as integrating legacy systems and the necessity for operator training alongside technological upgrades. This comprehensive assessment offers valuable insights into real-world issues and dependencies essential for successful Lean 4.0 integration in pharmaceutical quality management.

2.2Digital Transformation in Pharmaceutical Quality: Trends and Innovations

Ullagaddi (2024) did a full study on how the pharmaceutical industry's Quality Management Systems (QMS) and data security have changed since going digital. This study looked at the pros and cons of using technologies like blockchain, IoT, AI, and machine learning. It found some of the biggest problems, like integrating old systems and organizations that don't want to

change. Integration of technology, people, processes, and partnerships to improve quality, compliance, and operational excellence was highlighted in the study as an important part of the digital transformation process [28] .

Niazi (2024) explored the implementation of digital transformation in pharmaceutical quality management, focusing on innovative tools like electronic Quality Management Systems (eQMS), system integration, and data analytics. The article discussed how these technologies facilitate paperless and automated processes, enhance collaboration among departments, and improve data collection and analysis. The study highlighted the advantages of digital transformation, including reduced errors, easy access to data, and improved operational efficiency in quality management.

2.3Synergizing Lean and Digitalization for Predictive Management Excellence

Buer et al. (2021) investigated the combined impact of lean manufacturing and digitalization on operational performance. Their study revealed that both lean practices and factory digitalization independently enhance performance, but their concurrent implementation yields a synergistic effect, surpassing individual contributions. This shows how important it is to combine digital tools with lean methods to get better operational results [29].

Solke et al. (2022) looked into how predictive modeling and control based on machine learning can be used in lean manufacturing in the auto parts business.Their study demonstrated that incorporating machine learning techniques into lean systems enables predictive maintenance and process optimization, leading to improved flexibility and responsiveness in manufacturing operations. This approach enhances the ability to anticipate and address potential issues, thereby elevating overall production efficiency [30].

2.4Empirical Insights: Case Studies on Lean and Digital Integration in Pharma

Tetteh-Caesar et al. (2024)did a systematic review of case studies on how Lean 4.0 methods are being used in the pharmaceutical business. The study put together the most important lessons, benefits, and best practices from these integrations. It showed how improved automation, robotics, and AI have made businesses more flexible and productive. Concerns like regulatory limits and the need for gradual cultural adaptation were also talked about by the writers. This gave a complete plan for implementing Lean 4.0 successfully in pharmaceutical manufacturing.

Bevilacqua et al. (2015) presented a case study focusing on the reduction of changeover times in a pharmaceutical company's packaging line through the integration of various Lean practices. By implementing the Single-Minute Exchange of Die (SMED) methodology alongside tools like 5S, Kanban, and Total Productive Maintenance (TPM), the company achieved a significant decrease in batch change and changeover times, leading to a 25% increase in overall equipment effectiveness. The study provides practical insights into how Lean tools can be effectively combined to optimize manufacturing operations in the pharmaceutical sector [31].

da Silva and Gonçalves (2022) explored the application of Lean Digital Twins in the production lines of a pharmaceutical company. The study detailed how the adoption of a lean digital twin, a digital representation of a physical asset designed with Lean principles, enabled more dynamic adjustments to products and processes. This approach facilitated efficient problem identification and solution implementation, leading to cost reductions and improved operational agility. The authors emphasized the importance of developing flexible and innovative digital solutions tailored to the specific needs of pharmaceutical manufacturing [32].

2.5 Research Gap

Despite extensive research on Lean principles and digital transformation in pharmaceutical quality management, significant gaps remain. Existing studies primarily examine these concepts separately [28,5] with limited exploration of their integrated impact. While some research highlights synergies between lean and digitalization [29-30], large-scale empirical studies assessing their long-term effects are scarce. Challenges such as legacy system integration, organizational resistance [28, 22] and regulatory constraints remain inadequately addressed. Additionally, research on Lean Digital Twins in pharmaceutical manufacturing is still in its early stages [32], requiring further exploration of scalability and cost-benefit analysis. Moreover, the role of AI-driven predictive analytics in lean pharmaceutical operations is underexplored, despite its potential for enhancing quality management and operational agility. Addressing these gaps can provide a more comprehensive understanding of Lean 4.0's implementation, its regulatory alignment, and its transformative impact on pharmaceutical quality management. Addressing this gap will pave the way for predictive management and establish a roadmap for Pharma 5.0.

3. Research Methodology:

3.1 Research Design:

The study will use both quantitative and qualitative methods to fully look at how Lean principles and automation affect the long-term quality of pharmaceuticals. This allows for a holistic view, blending statistical analysis with expert insights.

3.2 Data Collection Methods:

1. **Primary Data:**
    - **Surveys**:

      The questionnaire will be distributed exclusively to professionals from

the pharmaceutical industry professionals to gather data on their experiences with Lean principles and digitalization in quality management. The study will focus solely on this industry to maintain relevance and specificity. The targeted sample size for the primary data collection shall be approximately 200 rparticipants, ensuring broad and diverse representation across functions such as Quality Assurance, Quality Control, Regulatory Affairs, Manufacturing, and IT/CSV. This focused approach will help derive meaningful insights relevant to pharmaceutical quality management practices.

2. **Secondary Data:**

- **Literature Review**:

  A comprehensive review of existing literature on Lean principles, digitalization, and quality management within the pharmaceutical industry.

- **Regulatory Reports**:

  Examination of pharmaceutical regulatory reports to assess industry trends and challenges related to quality sustainability and operational excellence.

3.3 Sampling Method:

A **random sampling method** will be employed to select participants from the pharmaceutical industry. The target population includes quality management professionals and regulatory personnel working within pharmaceutical companies. The survey sample shall ensure a diverse representation of professionals involved in quality processes and management within the industry. The population profile will focus on individuals with experience in implementing Lean principles and digital technologies in pharmaceutical quality management.

3.4 Key Variables of the study :

In this study, the independent variables (IVs) are Lean principles and digitalization approaches. Lean principles include key elements such as waste reduction, process improvement, and continuous quality monitoring, while digitalization approaches focus on the use of digital tools, automation, AI, predictive analytics, and real-time monitoring systems in quality management. The dependent variable (DV) is pharmaceutical quality sustainability, which will be evaluated through improvements in efficiency, compliance, cost-effectiveness, waste reduction, and predictive management in pharmaceutical quality processes.

3.5 Tools and Instruments:

A closed-ended questionnaire will be used to gather information for this project. The purpose of the questionnaire is to get detailed answers about how Lean principles, digital tools, and quality management are used in the pharmaceutical industry. It will focus on gathering quantifiable data to facilitate statistical analysis.

3.6 Data Analysis:

- **Quantitative Analysis**:

  SPSS will be used to do a quantitative study of the research data from the surveys. Our goal is to find the link between Lean principles, digitalization, and the results of pharmaceutical quality management using statistical methods like regression analysis, descriptive statistics, and association analysis. This will provide insights into how the integration of Lean principles and digitalization impacts quality sustainability and operational efficiency in the pharmaceutical sector.

- **Framework Development**:

An integrated framework combining Lean principles and digitalization will be developed based on the findings from both the primary and secondary data. This framework will aim to enhance quality sustainability and operational excellence within the pharmaceutical industry. Additionally, Key Performance Indicators (KPIs) for predictive management will be proposed to measure and track the performance and effectiveness of the integrated approach.

4.0Conclusion:

This study presents a comprehensive framework that integrates Lean principles with digitalization approaches to enhance pharmaceutical quality sustainability. By applying Lean methodologies focused on waste reduction and continuous process improvement alongside digital tools such as AI, automation, and real-time monitoring, the proposed framework aims to optimize operational excellence and regulatory compliance in the pharmaceutical industry. The implementation of this framework is expected to drive efficiency, reduce human error, and promote predictive management. These findings offer valuable insights for pharmaceutical leaders looking to improve quality management processes while remaining compliant with stringent industry regulations. The study contributes to both theoretical and practical advancements in quality management, providing a roadmap for future industry-wide adoption of Lean and digitalized practices.

5.0Limitations of the Study:

- Limited Generalizability: The study focuses specifically on the pharmaceutical sector, making it challenging to generalize the findings to other industries.

- Dependence on Self-Reported Data: Data collection through surveys may be subject to biases, such as social desirability bias, impacting the reliability of responses.
- Rapid Technological Changes: The fast-evolving nature of digital technologies might make some findings obsolete over time, limiting the long-term relevance of the framework.
- Regulatory Variations: Differences in regulatory environments across regions could affect the applicability of the framework in global contexts.
- Limited Sample Size: The sample size may be restricted due to the specific focus on pharmaceutical industry experts, which could limit the robustness of statistical analysis.

The future scope of this study is vast, as the integration of Lean principles and digitalization continues to evolve in the pharmaceutical sector. As more pharmaceutical companies transition towards Pharma 4.0, the framework developed in this research can be further refined to incorporate emerging technologies such as artificial intelligence, machine learning, and blockchain for enhanced traceability and security in quality management. Additionally, future research can explore the application of this framework in other areas of the pharmaceutical supply chain, such as manufacturing and distribution, to assess its broader impact. The study's findings can also be expanded to other highly regulated industries, such as biotechnology and medical devices, allowing for comparative analysis and adaptation. Furthermore, as regulatory environments become more stringent, the framework's adaptability to evolving guidelines can be studied, ensuring its relevance and applicability over time.

6.0 Expected Outcomes and significance of the study:

The research contributes significantly to the quality excellence of the pharmaceutical industry by providing a novel framework that integrates Lean

principles with digitalization for predictive quality management. It supports the transition towards Pharma 4.0, the study closes the gap between traditional quality management systems and digital transformation. It providesthe introduction of Key Performance Indicators (KPIs) for predictive management, serves as a strategic roadmap for fostering sustainability and continuous improvement within the sector. Expected outcomes of the study are as follows:

- **Development of an Innovative Framework**: Creation of a novel, integrated framework that combines Lean principles and digitalization approaches for predictive quality management in the pharmaceutical sector.
- **Operational Improvements**: Expected improvements in operational efficiency, compliance with regulatory standards, cost-effectiveness, and the reduction of errors and waste in quality management processes.
- **Enhanced Predictive Management**: Implementation of predictive management practices enabled by digital tools, including real-time monitoring and AI-driven analytics, to prevent quality issues proactively.
- **Industry-Wide Adoption**: A roadmap for pharmaceutical industry stakeholders that outlines steps for successful adoption of Lean and digitalization practices to ensure sustainability in quality management.

7.0 Practical Implications of the Study:

The practical implications of this study will be valuable for the pharmaceutical industry as it integrates Lean principles with digitalization to provide framework for predictive quality management. Here are the key practical implications:

- **Improved Process Efficiency**: Pharmaceutical companies can use the proposed framework to streamline their quality management processes, reduce waste, and improve overall efficiency.

- **Cost Reduction**: By incorporating the framework, companies can reduce operational costs by minimizing errors, improving automation, and optimizing resource allocation.
- **Enhanced Regulatory Compliance**: The integration of digital tools helps organizations align more effectively with regulatory requirements (e.g., FDA, EMA), ensuring compliance and reducing the risk of non-conformance.
- **Predictive Management**: With the use of predictive analytics, organizations can proactively identify potential risks, enhancing decision-making and preventing quality issues before they occur.
- **Quality Excellence**: Using both Lean and digitalization together creates a structured way to achieve continuous improvement, promote Quality excellence, and build a quality mindset within the company.
- **Pharma 5.0**: The study provides a roadmap to the pharmaceutical sector for Pharma 5.0, which emphasizes the use of advanced technologies like AI and IoT and integrates with human-centric approaches to improve patient-centric care.
- **Employee Skill Enhancement**: By implementing digitalization approaches, employees can upskill in data-driven quality management systems, improving their technical competencies in a digitized environment.

"**Chaptarization scheme of the study:**

- Introduction
- Literature Review
- Research Methodology
- Data Analysis and Interpretation
- Discussion and Findings
- Conclusion and Recommendations
- Limitations and Future Scope"

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Signature of the Supervisor/Guide **Signature of the Candidate**

(Seal of the Supervisor with University Name)

ANNEXURE – C

(On University Letterhead)

Directorate of Research & Development (DRD) where Research work will be carried out:

(wherever applicable)

The Synopsis of Shri Mir Parveez Shafi is in order, approved and recommended by DRD and forwarded to Dean or Director of Faculty of .... for consideration of registration for the degree of Doctor of Philosophy in the Integrating Lean Concept and Digitalization Approach : A Framework For Novel Predictive Management Excellence In Pharmaceutical Quality.

.

Place: **Signature with Seal of the Director, DRD**

Date:

ANNEXURE – D

(On University Letterhead)

Dean/Director of Faculties

Recommendation of the Dean or Director, Faculty of ……...…..

.....

The Synopsis of Shri Mir Parveez Shafi. is in order, approved and recommended by Director, DRD and forwarded to UREC/RAC for consideration of registration for the degree of Doctor of Philosophy in theIntegrating Lean Concept and Digitalization Approach : A Framework For Novel Predictive Management Excellence In Pharmaceutical Quality.

Place: **Signature with Seal of the**

Date: **Dean or Director of Faculty of …….**

Place: **Signature with Seal of the President,**
Jayoti Vidyapeeth Women's University,
Jaipur Date:

ANNEXURE – E

(On University Letterhead)

University Research Evaluation Committee (UREC) / Research Advisory Committee (RAC) Recommendation of the Chairman, UREC/RAC…… (*Name of Institute*)……

The Synopsis of Shri / Smt. / Ku……..... is duly approved on the recommendation of for registration in the program Doctor of Philosophy in the Integrating Lean Concept and Digitalization Approach : A Framework For Novel Predictive Management Excellence In Pharmaceutical Quality.

Place: **Signature with Seal of the Chairman,**

Date: **UREC/RAC**